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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/840,014	04/19/2001	Crystal C. Watkins	55802 (71699)	3068

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EXAMINER	
RUSSEL, JEFFREY E	

ART UNIT	PAPER NUMBER
1654	D

DATE MAILED: 06/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/840,014	WATKINS ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-7,13,14,35,44,51 and 53-76* is/are pending in the application.

4a) Of the above claim(s) *1,3-7,13,14,35,51,53-56 and 64-76* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *57, 58, and 61-63* is/are rejected.

7)☒ Claim(s) *59 and 60* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 April 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1. Applicant's election with traverse of the species sildenafil in Paper No. 7 is acknowledged. The requirement is still deemed proper and is therefore made FINAL.

Claims 1, 3-7, 13, 14, 35, 44, 51, 53-56, and 64-76 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. The formulas recited in these claims do not embrace sildenafil. Applicant timely traversed the restriction (election) requirement in Paper No. 7.

This application contains claims 1, 3-7, 13, 14, 35, 44, 51, 53-56, and 64-76 drawn to an invention nonelected with traverse in Paper No. 7. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

2. The substitute declarations under 37 CFR 1.67 filed April 7, 2003 are approved.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 61-63 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no original disclosure supporting the recitation in claim 61 that sildenafil increases nNOS or mRNA expression. Insulin is described in the specification as boosting nNOS and mRNA expression. However, the specification contrasts sildenafil with insulin by explaining that sildenafil augments NO activity. See, e.g., page 17, lines 12-20; page 92, lines

27-31; and page 94, lines 27-28. Applicants have not indicated where the original disclosure of the invention supports the new claim limitation.

4. Claim 62 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. There is no antecedent basis in the claims for the phrase "the patient" in claim 62. Note that claim 61 recites a mammal rather than a patient.

5. The effective filing date of instant claims 57, 59, and 60 is deemed to be April 19, 2000, the filing date of provisional application 60/198,545. Instant claims 57, 59, and 60 are deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of the '545 provisional application because the provisional application, under the test of 35 U.S.C. 112, first paragraph, discloses the claimed subject matter.

The effective filing date of instant claims 58 and 61-63 is deemed to be April 19, 2001, the filing date of the instant application. Instant claims 58 and 61-63 are not deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/198,545 because the provisional application, under the test of 35 U.S.C. 112, first paragraph, does not disclose treating a gstrointestinal disorder characterized by hypomotility (compare, e.g., page 20, lines 6-7, of the provisional application, which indicates that drugs which enhance the effect of NO, which include sildenafil, cause pyloric relaxation, whereas hypomotility would presumably be treated by drugs which cause contraction), and does not disclose the recitation in claim 61 that sildenafil increases nNOS or mRNA expression.

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claim 57 is rejected under 35 U.S.C. 102(a) and claims 61-63 are rejected under 35 U.S.C. 102(b) as being anticipated by the Bortolotti et al article (Gastroenterology, Vol. 118, pages 253-257). The Bortolotti et al article teaches treating patients with achalasia where there is an impairment of nitric oxide production by administering sildenafil, which blocks a phosphodiesterase type 5 that destroys nitric oxide-stimulated cGMP. See, e.g., the Abstract. With respect to instant claims 61-63, because the same active agent is being administered to the same patients by the same method steps, inherently nNOS and mRNA expression will be increased in the stomach, antrum, pylorus, or intestine in the method of the Bortolotti et al article to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the method of the Bortolotti et al article and Applicants' claimed method to shift the burden to Applicants to provide evidence that their claimed method is unobviously different than that of the Bortolotti et al article.

8. Claims 58, 61, and 63 are rejected under 35 U.S.C. 102(a) as being anticipated by the Watkins et al abstract (Gastroenterology, Vol. 118, No. 4, Suppl 2, page A669, Abstract 3667). The Watkins et al abstract teaches treating diabetic mice with diabetic gastropathy by administering sildenafil and zaprinast. The mice are identified as having reduced nNOS expression. With respect to instant claims 61 and 63, because the same active agent is being administered to the same patients by the same method steps, inherently nNOS and mRNA expression will be increased in the stomach, antrum, pylorus, or intestine in the method of the Watkins et al abstract to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the method of the Watkins et al abstract and

Applicants' claimed method to shift the burden to Applicants to provide evidence that their claimed method is unobviously different than that of the Watkins et al abstract.

9. Claims 58 and 61-63 are rejected under 35 U.S.C. 102(e) as being anticipated by Gmunder et al (U.S. Patent Application Publication No. 2002/0012633). Gmunder et al teach the administration of sildenafil citrate in chewing gum form to treat esophageal spasms, dysphagia, and gastroparesis associated with diabetes. See, e.g., the abstract and paragraph [0088]. With respect to instant claims 61-63, because the same active agent is being administered to the same patients by the same method steps, inherently nNOS and mRNA expression will be increased in the stomach, antrum, pylorus, or intestine in the method of Gmunder et al to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the method of Gmunder et al and Applicants' claimed method to shift the burden to Applicants to provide evidence that their claimed method is unobviously different than that of Gmunder et al.

10. Applicant's arguments filed April 7, 2003 have been fully considered but they are not persuasive.

The rejection over the Bortolotti et al article (Gastroenterology, Vol. 118, pages 253-257) is maintained. The Bortolotti et al article was published in February 2000, not in April 2000 as was indicated in Applicants' remarks, and accordingly the Bortolotti et al article is available as prior art against Applicants' claims at least under 35 U.S.C. 102(a). For those of Applicants' claims not entitled to the benefit of the filing date of the provisional application 60/198,545, the Bortolotti et al article is available as prior art under 35 U.S.C. 102(b).

Claims 57, 59, and 60 are not rejected over the Watkins et al abstract (Gastroenterology, Vol. 118, No. 4, Suppl 2, page A669, Abstract 3667) because these claims are entitled to the

benefit of the filing date of provisional application 60/198,545, and therefore the Watkins et al abstract is not prior art against these claims. The Watkins et al abstract is applied against those elected claims which are not entitled to the benefit of the filing date of the provisional application. Gastroenterology, Vol. 118, No. 4, Supple. 2, was received by the Patent Office library on May 9, 2000, and the meeting date for presentation of the abstracts was May 21-24, 2000, and therefore the Watkins et al abstract is prima facie available as prior art against these claims under 35 U.S.C. 102(a). The Snyder declaration filed April 7, 2003 is not sufficient to show that the Watkins et al abstract was not "by another" because the Snyder declaration is incomplete. Only the first portion of paragraph 3 of the declaration is present in the copy filed with the Office, and paragraph 4 is entirely missing from the declaration. Given the statement made in paragraph 5 of the Snyder declaration, the examiner expects that when a complete copy of the declaration is filed, the declaration will establish that the Watkins et al abstract is not "by another" and is not available as prior art under 35 U.S.C. 102(a).

Claims 57, 59, and 60 are not rejected over Gmunder et al (U.S. Publ. No. 202/0012633) because these claims are entitled to the benefit of the filing date of provisional application 60/198,545, and because the disclosure of Gmunder et al relied upon in the rejection is not disclosed in any of its priority documents (09/286,818 and WO 00/35298) which have a filing date earlier than Applicants' effective filing date. Gmunder et al remains available as prior art under 35 U.S.C. 102(e) against instant claims 58 and 61-63.

11. Claims 59 and 60 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. While the Bortolotti et al article (Gastroenterology, Vol. 118,

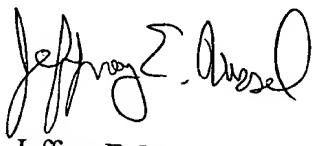
pages 253-257) is prior art against these two claims, the reference's disclosure of the treatment of achalasia and the effects of sildenafil on esophageal motility does not suggest the treatment of disorders characterized by diarrhea or constipation or of disorders associated with diabetes.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (703) 306-3220. The fax number for Art Unit 1654 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

June 5, 2003